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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/698,824	10/30/2003	Bob B. Buchanan	416272005602	1263

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MORRISON & FOERSTER LLP  
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EXAMINER

KAM, CHIH MIN

ART UNIT PAPER NUMBER

1656

DATE MAILED: 12/14/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

**Office Action Summary**

Application No.

10/698,824

Applicant(s)

BUCHANAN ET AL.

Examiner

Chih-Min Kam

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1) ☐ Responsive to communication(s) filed on \_\_\_\_.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4) ☒ Claim(s) 27-45 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_ is/are allowed.
- 6) ☐ Claim(s) \_\_\_\_ is/are rejected.
- 7) ☒ Claim(s) 27-45 is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_ are subject to restriction and/or election requirement.

**Application Papers**

- 9) ☒ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 30 October 2003 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

**Priority under 35 U.S.C. § 119**

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
  2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_.
  3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

**Attachment(s)**

- |  |   |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892)  | 4) <input type="checkbox"/> Interview Summary (PTO-413)<br>Paper No(s)/Mail Date. ____. |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)   | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152)             |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)<br>Paper No(s)/Mail Date <u>12/8/03</u> . | 6) <input type="checkbox"/> Other: ____.  |

### **DETAILED ACTION**

1. In the preliminary amendment filed October 30, 2003, claims 1-26 have been cancelled, and new claims 27-45 have been added. Therefore, claims 27-45 are examined.

#### ***Informalities***

The disclosure is objected to because of the following informalities:

2. The specification cites amino acid sequences at page 137, lines 19 and 21-22, however, there is no sequence identifier, "SEQ ID NO:" provided. Applicants must comply with the requirements of the sequence rules (37 CFR 1.821-1.825) and provide a paper copy of Sequence Listing and a computer readable form (CRF) containing all the sequences.

#### ***Claim Rejections - 35 USC § 112***

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

3. Claims 39, 40, 42 and 43 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.
4. Claims 39 and 40 are indefinite because the claim recites the allergenic food protein with reduced allergenicity, which has at least disulfide bond reduced and blocked with a disulfide bond, "further" comprising added thioredoxin and nicotinamide adenine dinucleotide phosphate-thioredoxin reductase (NTR), it is not clear why thioredoxin and NTR are added to the food protein which has already at least one disulfide bond reduced.
5. Claims 42 and 43 are indefinite because the claim recites allergenic food, but is dependent from claim 40, which recites allergenic food protein.

***Claim Rejections - 35 USC § 102***

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

6. Claims 27-29 and 33-40 are rejected under 35 U.S.C. 102(b) as being anticipated by Axelsson *et al.* (FEBS LETTERS 53, 40-43 (April 1975)).

Axelsson *et al.* discloses egg white lysozyme is reduced with dithioerythritol, and the reduced lysozyme is then reacted with the oxidized form of glutathione (GSSG) to form a mixed disulfide protein (page 40, paragraph 2.2; claims 27-29 and 33-40). Although the reference does not specifically indicate the mixed disulfide of lysozyme and GSSG has reduced allergenicity, lysozyme is a known allergenic protein from egg (see Art of Record below) and the protein is modified by the same procedure (i.e., reacting with a reducing agent, and then blocking with a physiological disulfide, GSSG) as the claimed protein, thus, it would be expected that the mixed disulfide of lysozyme and GSSG has reduced allergenicity, which meets the criteria of the claimed protein. Although the reducing agent of the reference, dithioerythritol is different from the reducing agents used in the instant application, it has reduced a disulfide bond of lysozyme, which makes dithioerythritol as effective as other reducing agents indicated in the claims.

***Claim Rejections - 35 USC § 103***

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are

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such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

7. Claims 27-45 are rejected under 35 U.S.C. 103(a) as being unpatentable over Buchanan *et al.* (U. S. Patent 6,190,723, filed March 23, 1998) in view of Rosendahl *et al.* (US 2004/0018586, priority date being the filing date of provisional application, 60/204,617, filed May 16, 2000).

Buchanan *et al.* disclose a method of decreasing the allergenicity of an allergenic food protein by reacting the protein with thioredoxin, NTR and NADPH, or DTT in the presence of thioredoxin, and provide a hypoallergenic ingestible food by pre-treating the food with thioredoxin in the presence of NTR and NADPH, where the food can be beef, milk, soy, rice or wheat (column 11, lines 16-30; Examples 10, 11, 18, 33-38). However, Buchanan *et al.* do not disclose the subsequent reaction of the reduced allergenic food protein with a physiological disulfide to minimize reoxidation of the reduced protein or to stabilize the reduced protein.

Rosendahl *et al.* disclose a number of cysteine blocking agents such as cystamine and oxidized glutathione can be used to react with free cysteine residues of a protein to form a mixed disulfide thus stabilizing the protein and preventing multimerization and aggregation of the protein (paragraph [0041]).

At the time of invention was made, it would have been obvious that one of ordinary skill in the art has been motivated to combine the two references to treat an allergenic food protein or an allergenic food with a reducing agent to reduce allergenicity of the protein or food as taught by Buchanan *et al.* and further to treat the reduced food protein with a disulfide such as glutathione or cystamine as taught by Rosendahl *et al.* (claims 27-45) because the further treatment of the reduced allergenic protein with the disulfide would stabilize the protein and

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prevent multimerization or aggregation of the protein. Thus, the combined references result in the claimed invention and was, as a whole, prima facie obvious at the time the claimed invention was made.

***Conclusion***

8. No claims are allowed.

***Art of Record***

Sampson (Book of Abstracts, 216th ACS National meeting, Boston, August 23-27 (1998), AGFD-005) discloses lysozyme is one of major allergens in eggs.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Chih-Min Kam whose telephone number is (571) 272-0948. The examiner can normally be reached on 8.00-4:30, Mon-Fri.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Kathleen Kerr can be reached at 571-272-0931. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

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Chih-Min Kam, Ph. D.

Patent Examiner

A handwritten signature in black ink, appearing to read 'Chih-Min Kam', with a long horizontal stroke extending to the right.

**CHIH-MIN KAM**  
**PATENT EXAMINER**

CMK

December 09, 2005